No. 10-972

In the Supreme Court of the United States

ELI LILLY AND COMPANY, PETITIONER

v.

SUN PHARMACEUTICAL INDUSTRIES LTD., RESPONDENT

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The doctrine of obviousness-type double patenting forbids a party from twice patenting the same invention or an obvious variation thereof. This doctrine, which is increasingly obsolete because of congressional changes to the patent statutes, exists to prevent the "timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *In re van Ornum*, 686 F.2d 937, 943-944 (C.C.P.A. 1982).

In this case, petitioner's first patent on the drug at issue disclosed two utilities—an antiviral and an anticancer utility—but failed to mention that petitioner's own post-application tests showed that the compound "proved to be very toxic during *in vivo* tests and thus *not suitable for development as an antiviral agent*." In other words, only the second, anticancer utility was viable. Yet petitioner then obtained a *second* patent on the compound for the anticancer utility, extending its monopoly by two-and-a-half years.

Against this backdrop, the question presented is whether the court of appeals' unanimous ruling — which petitioner concedes "correctly described the law of obviousness-type double patenting" — correctly applied that law to the patents here, where the later patent claimed the same utility described in the specification of the earlier patent.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondent Sun Pharmaceutical Industries Ltd. states that it has no parent corporation and that no publicly held company owns 10 percent or more of the company's stock.

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INTRODUCTION

The petition fails to satisfy the criteria for a grant of certiorari, and should therefore be denied.

Most fundamentally, petitioner seeks to have this Court correct what petitioner believes is an erroneous application of settled precedent. Petitioner does not take issue with the precedents relied on below, but instead says they were "misread[]" or applied "out of context" or do not "support" the decision below. Pet. 24-25, 27. To be sure, petitioner also asserts that the court "creat[ed] a new bright-line rule" that "transformed the doctrine of double patenting." Pet. i. But petitioner expressed a different view in its rehearing petition, stating: "*Having correctly described the law of obviousness-type double patenting in its opinion*, the Panel then failed to apply it." *Infra* at 15. As we will show, the unanimous panel here both "correctly described" *and* correctly applied the law. But even if the court below had erred, certiorari is not warranted "when the asserted error consists of * * * misapplication of a properly stated rule of law." Rule 10. Such is the case here.

Nor does the petition satisfy the other criteria for certiorari. Citing dictum from *Miller* v. *Eagle Manufacturing Co.*, 151 U.S. 186 (1894), a 19th century case involving patents on springs used in a plow apparatus, petitioner attempts to demonstrate a conflict with this Court's rulings. But *Miller* involved *same-invention-type* double patenting, not *obviousness-type* double patenting, and petitioner concedes that only the latter is involved here. Moreover, *Miller* itself relied heavily on the first patent's specification in conducting its double patenting analysis. And the other cases cited by petitioner—whether precedents of this

Court or the lower courts—generally do not involve patents on chemical compounds, which raise unique issues, since their utility is not self-evident and thus requires reference to the patent's specification.

Review is also unwarranted because amendments to the patent statute have rendered double patenting law increasingly obsolete. Under pre-1995 law, a patent term began when the patent was issued. Thus, if a patent application later spawned multiple patents through continuations, there might be multiple issue dates—and the possibility of double patenting. But since 1995, no matter how many patents issue from a patent application, every patent term generally ends on the same date—twenty years after the filing date. Because such patents all expire together, there is far less potential for double patenting and far less need for the doctrine—which, as the Federal Circuit has observed, guards against "improper extension of patent rights through the use of divisional and continuation applications, *at least for patents issued from applications filed prior to the amendment of 35 U.S.C. § 154 to create twenty-year terms running from the date of the earliest related application.*" *Boehringer Ingelheim Int'l GmbH* v. *Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010) (emphasis added). With every passing day, this pool of live patents shrinks—and by 2015 it will largely disappear.

Even now, double patenting cases arise only a few times annually, and the particular issue here arises even less often—to our knowledge, only four times in the last decade. Nor is the question presented likely to arise again, as patentees can easily address it during prosecution. Indeed, petitioner could have avoided the ruling below in multiple ways—for example, by terminally disclaiming the later patent, by not includ-

ing the anticancer utility in the earlier patent, or by including anticancer method *claims* along with the anticancer disclosure. Future patentees are virtually certain to follow these approaches (most already do), which require minimal effort. Thus, for this reason too, the question presented is not the kind of "important and recurring issue" that warrants review. *California* v. *Am. Stores Co.*, 492 U.S. 1301, 1306 (1989) (O'Connor, Circuit J.).

Further, equitable considerations counsel against review. Petitioner notes that it first sought to patent gemcitabine for use in fighting viruses, and only later sought to patent gemcitabine for fighting cancer. But nowhere does petitioner acknowledge that, when applying for its second patent, it failed to mention its own studies' conclusion that "[gemcitabine] proved to be very toxic during *in vivo* tests and thus *not suitable for development as an antiviral agent.*" C.A. App. A314-A318, A315 (emphasis added) (Lilly internal memorandum).

In other words, there was only one patentable invention here—gemcitabine as an anticancer agent. Yet, by never telling the PTO that gemcitabine's purported antiviral utility did not pan out, petitioner obtained *two* patents. Thus, far from "subvert[ing] the disclosure policies underlying the patent statute" (Pet. 33), the decision below promotes them. And petitioner's non-disclosure confirms that combating cancer was not simply the "best mode" of using gemcitabine (Pet. 10-11); it was the *only* mode. To find double patenting on these facts makes perfect sense.

Moreover, insofar as the petition attempts to raise broader double patenting questions, those questions were not "pressed in or considered" on the merits be-

low—and are therefore "waived." *E.g.*, *Stolt-Nielsen S.A.* v. *AnimalFeeds Int'l Corp.*, 130 S. Ct. 1758, 1767 n.2 (2010). For example, petitioner says the decision below contravenes 35 U.S.C. §§ 101, 102, 103, and 120. But as petitioner conceded below, § 101 is the basis for "same invention double patenting," which is "clearly not applicable." *Infra* at 16, 29. Petitioner cited the other statutes only in passing, and not for the propositions asserted here. Thus, even if the question presented were certworthy (it is not), the Court should await a proper vehicle to resolve it.

Finally, on the merits, the decision below was a straightforward application of settled legal principles to these particular (perhaps unique) facts. Specifically, although double patenting generally turns on the claims, a modified rule applies to chemical compounds. And for good reason: Such compounds are not patentable absent utility, yet their utility is generally not self-evident from the claims describing the compound. Thus, referring to specifications disclosing the utility of the claimed compounds only makes sense. See generally *Geneva Pharm., Inc.* v. *GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003); *Pfizer, Inc.* v. *Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008). To be sure, the dissent from denial of rehearing questioned those precedents. But even if there were a basis for revisiting them (and there is not), petitioner does not question them.

Certiorari should therefore be denied.

STATEMENT

This appeal arises under the Hatch-Waxman Act ("Act" or "Hatch-Waxman"), which governs FDA approval of new and generic drugs. See 21 U.S.C. § 355. Hatch-Waxman allows companies seeking to market generic versions of FDA-approved drugs to file abbreviated new drug applications (ANDAs) that rely on safety and efficacy data earlier submitted as part of a new drug application (NDA). *Id.* § 355(j)(2).

In 2006, respondent filed an ANDA requesting approval to market a generic version of petitioner's Gemzar product, an anticancer drug containing the active ingredient gemcitabine. Respondent's ANDA certified that the two patents covering Gemzar—the '614 and '826 patents—were invalid or not infringed by respondent's product. See *id.* § 355(j)(2)(A)(vii)(IV).

Respondent thereafter sued petitioner to obtain a declaration of invalidity or non-infringement freeing respondent to enter the marketplace. Applying settled precedent, the courts below held that the asserted claims of the '826 patent were invalid because they were not "patentably distinct" from a claim of the '614 patent, and thus amounted to impermissible "double patenting." As here (Pet. 18-27), petitioner maintained that this reasoning misapplied Federal Circuit precedent. See *infra* at 14-16. To appreciate why that is not so—which is not to suggest that error correction is a basis for certiorari—it is important to understand (A) the distinctive features of chemical compound patents; (B) petitioner's strategic decision to risk an obviousness-type double patenting challenge, and (C) the rationale of the decision below.

A. Distinctive features of patents and legal principles in the chemical arts

"[T]he concept of utility has maintained a central place in all * * * patent legislation, beginning with the first law in 1790 and culminating in the present law's" protection of inventions that, among other things, are "useful.'" *Brenner* v. *Manson*, 383 U.S. 519, 529 (1966) (footnote omitted). Unlike in fields involving inventions whose utility may be self-evident or well-established, obtaining a patent for a chemical compound requires the inventor to demonstrate a utility that is "specific" and "substantial." *Id.* at 534. In the chemical arts, "[i]t is the properties of [the] compounds * * * that give them their utility." *In re Pleuddemann*, 910 F.2d 823, 827 (Fed. Cir. 1990).

Patent claims that describe chemical compounds, however, usually lack such information. Unlike with an article of manufacture or an apparatus, a bare compound claim merely depicts the chemical formula of the molecule using graphical drawings of its structure or systematic naming convention (gemcitabine, for example, is 1-(2-oxo-4-amino-1H-pyrimidin-1-yl)-2-desoxy-2,2-difluororibose). While such a claim is "drawn to a compound having a certain physical property," it does not, "[s]tanding alone, * * * adequately disclose the patentable bounds of the invention." *Geneva*, 349 F.3d at 1385.

Accordingly, for double patenting purposes, courts do not consider a compound claim "in a vacuum, as a simple compound." *Ibid.* Rather, courts review the patent specification both to determine the full scope of the compound claim, including its "disclosed utility," and to identify differences between the claims being compared. *Ibid.*; see also *In re Basell Poliolefine*

Italia S.P.A., 547 F.3d 1371, 1378-1379 (Fed. Cir. 2008) (specifications are used "to answer the question whether [chemical] claims merely define an obvious variation of what is earlier disclosed and claimed"); *Pfizer*, 518 F.3d at 1363 n.8 (same). In short, due to the nature of claims in the chemical arts, reference to the specification is necessary when conducting a double patenting analysis where in other contexts it might not be.

Moreover, chemical compounds sometimes have multiple utilities. When multiple utilities are disclosed in a patent specification, courts do not consider only some of them: "There is no basis in law for ignoring *any* property in making * * * a comparison" for obviousness or double patenting. *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (evaluating obviousness for patentability) (emphasis added). Instead, "[f]rom the standpoint of patent law, a compound and all of its properties are inseparable." *Ibid.*

B. Petitioner's patent strategy

Gemcitabine is a "nucleoside analog," a class of compounds designed to interfere with DNA replication within the human body. Both cancer and viruses rely on DNA replication to multiply—viruses by inserting their DNA into the host cell's DNA, and cancer by overproducing cells containing malignant DNA. Thus, "nucleoside analogs" treat both viral infections and cancer by disrupting the DNA replication process.

Nucleoside analogs do this by fooling the human body into thinking that they are legitimate nucleosides—*i.e.*, true building blocks of DNA. Because they so closely resemble nucleosides, the body sometimes mistakes them for the real thing and incorpo-

rates them into DNA. Then, the minor structural differences between the analog and the real thing interfere with DNA synthesis, leading to cell death.

1. Petitioner's original application claiming gemcitabine as an antiviral agent and its discovery that gemcitabine was too toxic for use against viruses

In its original 1983 application seeking patent protection for a class of nucleoside analogs, petitioner claimed that thousands of compounds, including gemcitabine, were useful to treat viral infections not cancer. To show that these analogs were useful to treat viruses, petitioner disclosed testing only of one distinct compound known as "DFAT"; it disclosed no testing of gemcitabine.

By mid-1984, moreover, petitioner had determined that gemcitabine was *not* useful to fight viruses. As the August 1984 minutes of petitioner's Biological and Chemical Evaluations Subcommittee stated: "Although some of these analogs possessed activity against * * * viruses, development was curtailed by their toxicity." C.A. App. A247. A later memo elaborated that, by December 1984, petitioner had concluded that gemcitabine "proved to be very toxic during *in vivo* tests and thus *not suitable for development as an antiviral agent*." C.A. App. A314-A318, A315 (emphasis added).

This presented a problem for petitioner, because its original application failed to identify *any* other use for gemcitabine. The claims specified no use at all, and the specification discussed only antiviral use—when, as noted, petitioner had concluded that gemcitabine was not a "suitable" antiviral agent. Thus, to

protect itself from a patent challenge based on lack of utility, petitioner needed an *alternative* utility to support a compound claim to gemcitabine.

2. Petitioner's continuation-in-part application and its failure to disclose that gemcitabine was unsuitable for treating viruses

In December 1984, petitioner solved that problem by filing a "continuation-in-part" application referencing test results showing that gemcitabine was a "particularly preferred compound" for treating cancer:

> In addition to the antiviral utility of the present compounds, certain of the compounds of the present invention have also demonstrated excellent oncolytic activity in standard cancer screens. A particularly preferred compound with this utility is the compound of Example 8, [gemcitabine].

Pet. 3a-4a. Before this anticancer disclosure, petitioner had never singled out gemcitabine, which, as noted, was just one compound among thousands in a genus described in the specification.

The petition highlights Lilly's statement during prosecution that it was not relying on the newly disclosed anticancer data to "support the utility of the claimed invention." Pet. 11. But when it made that statement, petitioner was still pursuing broad claims covering thousands of compounds, claims that petitioner asserted were supported by *antiviral* data. It was not until much later that petitioner added the specific compound claim singling out gemcitabine, which petitioner had concluded was *not* a "suitable" antiviral agent. Petitioner never told the PTO that, in fact, anticancer treatment was gemcitabine's *only* viable utility.

3. Petitioner's application for what became the '826 patent

On the same day that it filed the 1984 continuation-in-part application for what became the '614 patent—the application that disclosed gemcitabine's anticancer utility—petitioner filed a separate patent application that included claims directed to methods of treating cancer by administering gemcitabine. That separate application later issued as the '826 patent, the relevant claims of which, had they not been invalidated, would have expired in November 2012, two-and-a-half years after the '614 patent expired. It is the anticancer method claims in the '826 patent—which petitioner disclosed in the '614 patent—that petitioner asserted against respondent, and that the courts below invalidated.

Risking this result was petitioner's choice. Petitioner had at least *three* ways of disclosing the anticancer utility of gemcitabine while avoiding a double patenting challenge. First, petitioner could have terminally disclaimed the '826 patent. See 35 U.S.C. § 353; M.P.E.P. § 804.02 (8th ed., Rev. 7 (July 2008)). Second, petitioner could have declined to add the anticancer disclosure to the December 1984 continuation-in-part application and, instead, relied solely on the antiviral utility (if, as petitioner maintains, that utility was sufficient to support the patent). See *In re Davies*, 475 F.2d 667, 671 (C.C.P.A. 1973) ("there is no specific statutory requirement that compels an applicant to disclose all properties of chemical compounds or compositions in his application"). Third, rather than file a separate patent application, petitioner could have included anticancer method claims in its continuation-in-part application. See 35 U.S.C. § 121; *Pfizer*, 518 F.3d at 1358-1362.

Any of these routes would have avoided double patenting. Yet petitioner took none of them. Instead, it forged ahead and obtained a second patent, securing a two-and-a-half-year extension on its monopoly.

C. The decisions below

The courts below ruled that petitioner made a poor strategic gamble. The district court found the '826 patent invalid under the Federal Circuit's decisions in *Geneva* and *Pfizer*, which held that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Geneva*, 349 F.3d at 1385-1386; *Pfizer*, 518 F.3d at 1363. Petitioner sought reversal, arguing that the district court misapplied those decisions, but the Federal Circuit affirmed and denied rehearing en banc.

1. The district court's decision

The district court observed that obviousness-type double patenting analysis involves two steps: "(1) the court construes the claims of the earlier and later patents and determines their differences; and (2) the court determines whether those differences render the claims patentably distinct." Pet. 27a (citing *Pfizer*, 518 F.3d at 1363). In performing the first step, the court followed precedent holding that, when the earlier claim is a compound claim, the court "may examine the specifications of both patents to determine any overlap in the claim scope for double patenting purposes." Pet. 28a. Accordingly, the district court found a double patenting violation:

> Claim 12 of the '614 Patent [the compound claim] fails to adequately describe the bounds of the claimed invention, and therefore, this court may use the specification disclosure in the '614

> Patent, using gemcitabine for cancer chemotherapy treatment, to interpret the coverage of Claim 12. * * *; *Geneva*, 349 F.3d at 1385. Clearly, when properly considering the anti-cancer use of gemcitabine expressly disclosed in the '614 Patent specification, there is an overlap of Claim 12 of the '614 Patent and Claims 2, 6 and 7 of the '826 Patent.

Pet. 30a. Thus, "[b]ased on the clear and convincing evidence," the court concluded that "[the] claims are not patentably distinct." Pet. 35a.

2. The court of appeals' decision

A unanimous Federal Circuit panel affirmed, explaining in detail why its conclusion was compelled by *Geneva* and *Pfizer*. As in those cases, "to ascertain the scope of the earlier patent's claim to the compound itself," the court "had to examine the specification of the earlier patent, including the compound's disclosed utility." Pet. 8a. Having done so, the Federal Circuit held that "the two patents were not 'patentably distinct' and thus the later patent was invalid for obviousness-type double patenting, because the later patent 'claim[ed] nothing more than [the earlier patent's] disclosed utility as a method of using the * * * compound.'" *Ibid.* (quoting *Geneva*, 349 F.3d at 1385-1386)).

The court went on to explain that the same was true in *Pfizer*: (1) "the earlier patent claimed several compounds and the specification disclosed their use in treating inflammation and inflammation-associated disorders"; and (2) "[t]he later patent then claimed a method of using these compounds for treating inflammation, inflammation-associated disorders, and specific inflammation-associated disorders, including arthritis, pain, and fever." Pet. 9a. "After re-

jecting the patentee's objection to our consideration of the specification of the earlier patent," the Federal Circuit "determined that the later patent 'merely claims a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent.'" Pet. 9a (quoting *Pfizer*, 518 F.3d at 1363 & n.8). Accordingly, "the later patent was invalid for obviousness-type double-patenting." *Ibid.*

Petitioner did not dispute that *Geneva* and *Pfizer* were good law. Instead, petitioner "attempt[ed] to distinguish" those cases on the basis that, "in both cases, the specification of the earlier patent disclosed a single use for the claimed compound, which was an essential part of the patented invention and thus necessary to patentability." Pet. 9a. Here, petitioner said, the specification of the '614 patent disclosed *two* uses—treating viral infections and cancer—and "the antiviral use provided the essential utility necessary to the patentability of the '614 patent's claim to gemcitabine." Pet. 10a.

But as the Federal Circuit explained in rejecting this argument, "Lilly's classification of *Pfizer* is factually erroneous because [in that case] the earlier patent's specification unambiguously disclosed *more than one utility* for the claimed compound"—as here. Pet. 10a. "Moreover, the analysis in the *Pfizer* decision shows that obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." Pet. 11a-12a. The court held that this principle compelled a finding of double patenting here.

The Federal Circuit denied en banc review. The dissent questioned *Geneva* and *Pfizer*, but did not dispute that they controlled the outcome. See Pet. 138a-139a. Nor does petitioner seek to overrule those decisions. Pet. 24-27. Instead, petitioner asks this Court to correct the lower court's application thereof. As explained below, there is no basis for doing so.

REASONS FOR DENYING THE PETITION

I. Petitioner Principally Seeks To Have This Court Engage In Error Correction, And Has Waived The Principal Statutory Issues Now Pressed In Its Petition For Certiorari.

The petition is loaded with rhetoric asserting that the unanimous decision below "cut [double patenting] doctrine free from its jurisprudential moorings" and distorted a "stable area of law." Pet. 2. But petitioner's own briefs below confirm that this premise is false, and certiorari is not designed for "correction of error in particular cases." *Watt* v. *Alaska*, 451 U.S. 259, 275 n.5 (1981) (Stevens, J., concurring). Moreover, the broader statutory issues that petitioner now raises were neither pressed in the Federal Circuit nor considered by that court on the merits. Thus, even if the question presented were otherwise worthy of review—and it is not (see Parts I.A., II-IV)—the Court should await a case in which the relevant legal issues could be fully considered.

A. Petitioner previously conceded that the court below correctly described the law of double patenting, challenging only its application of that law.

The petition makes sweeping assertions that the Federal Circuit "creat[ed] a new bright-line rule" that "transformed the doctrine of double patenting."

Pet. i. Before the court below, however, Lilly told another story—that the panel merely misapplied *Geneva* and *Pfizer* to the particular facts at issue.

Indeed, petitioner's rehearing petition repeatedly sounded the theme that the court simply "failed properly to apply *Geneva*" or erred "[i]n attempting to apply *Geneva*'s 'same invention' rule." Combined Pet. for Panel Reh'g and Reh'g En Banc of Defendant-Appellant Eli Lilly and Co. 6, 8 (No. 2010-1105) (filed Aug. 25, 2010); see *id.* at 3 (the panel "misapplie[d] *Geneva* to a fact pattern where it cannot lawfully apply"); *id.* at 8 (criticizing "[t]he panel's application of *Geneva*").[1] Petitioner did not ask that this precedent be overruled. Rather, it stated: "*Having correctly described the law of obviousness-type double patenting in its opinion*, the Panel then failed to apply it." *Id.* at 7. Petitioner's reports that the ruling below destabilized the law are thus greatly exaggerated.

Even today, petitioner does not suggest that *Geneva* and *Pfizer* were wrongly decided or presented an incorrect framework for resolving this case. Indeed, in its less hyperbolic moments, petitioner asserts only that those precedents were "misread[]" or applied "out of context," or do not "support" the decision below. Pet. 24-25, 27. But even if the unanimous panel below had misapplied governing precedent—a point we refute below—Supreme Court Rule 10 could not be clearer: "A petition * * * is rarely granted when the asserted error consists of * * * misapplication of a

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[1] Petitioner raised similar points before the merits panel. Br. of Defendant-Appellant Eli Lilly and Co. 18-23 (No. 2010-1105) (filed Dec. 22, 2009) (attempting to distinguish *Geneva* and *Pfizer* factually); *id.* at 23 (criticizing "the District Court's application of *Geneva*"); *id.* at 28-29 (same).

properly stated rule of law." This alone warrants denying certiorari.

B. Petitioner's waiver of the principal statutory issues it now presses makes this case a poor vehicle to resolve the question presented.

Perhaps aware of this difficulty, petitioner tries to raise new issues not "pressed in or considered" on the merits below—issues that are "waived." *E.g.*, *Stolt-Nielsen*, 130 S. Ct. at 1767 n.2.

For example, petitioner says the decision below is inconsistent with 35 U.S.C. §§ 101, 102, 103, and 120. But as petitioner's merits brief in the court of appeals conceded, § 101 is the basis for "same invention double patenting," which is "clearly not applicable." Br. of Defendant-Appellant Eli Lilly and Co. 16, 17 (No. 2010-1105) (filed Dec. 22, 2009). Moreover, petitioner mentioned the other statutes it now invokes only in passing, and not for the points that petitioner presses here. *Id.* at 8, 21 (§ 102); *id.* at 18, 21 (§ 103); *id.* at 3, 8, 22 (§ 120).

As a result, the panel below never analyzed petitioner's newfound statutory issues on the merits, and the en banc court denied review. It follows that, even if the question presented were otherwise certworthy, this case would not present a proper vehicle to decide it.

II. The Double Patenting Question On Which Petitioner Seeks Review Lacks Recurring Significance.

Denial of certiorari is independently warranted on the ground that the double patenting issues at stake arise in few cases, and thus do not involve the sort of

"important and recurring issue" that warrants certiorari. *Am. Stores*, 492 U.S. at 1306 (O'Connor, Circuit J.). To the contrary, double patenting doctrine is increasingly obsolete because of statutory changes limiting patentees' ability to "evergreen" their original applications into extra-long patent terms. Nor does any current conflict of authority in the lower courts warrant review.[2] And to the extent that issues similar to those presented by these anomalous facts arise, patentees can avoid any risk of double patenting by taking proper steps during the prosecution stage.

A. Due to Acts of Congress, double patenting doctrine is falling into disuse, and the particular issue and facts here are rare.

1. On account of Congress's changes to the patent statute—changes not mentioned by petitioner—double patenting is a doctrine of greatly diminishing significance. "The double patenting doctrine was developed during an era when the term of a patent was dependent on its issue date, and permitting an applicant to obtain a series of patents with claims directed to the same subject matter would result in timewise extension of the expiration date of the monopoly for a single invention." E. Evans & J. Jacobson, *Double*

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[2] Amicus Washington Legal Foundation (WLF) attempts (at 10-16) to show conflict among the circuits by pointing to decisions issued long before the Federal Circuit was created in 1982. But none of these cases involve chemical compound patents, and the *most recent* is from 1963—nearly 50 years ago. Br. 15. That WLF must reach back so far, and to such inapposite cases, to concoct a stale conflict confirms the rarity of the question presented.

Patenting Recapitulated, 87 J. Pat. & Trademark Off. Soc'y 625, 626 (2005). "Under current law," however, "patents issuing from applications filed on or after June 8, 1995 have a term expiring twenty years from the earliest claimed priority [*i.e.*, application] date. Therefore, successively issuing patents all claiming priority back to the same application now have the same expiration date. Thus, unless a patent term extension is granted, the date on which a patent monopoly will end will not be extended by permitting a series of patents directed to the same invention to issue." *Ibid.* (footnote omitted); see 35 U.S.C. § 154.

Not surprisingly, the Federal Circuit has called the doctrine of obviousness-type double patenting "an important check on improper extension of patent rights * * * *at least for patents issued from applications filed prior to the amendment of 35 U.S.C. § 154 to create twenty-year terms running from the date of the earliest related application.*" *Boehringer Ingelheim*, 592 F.3d at 1346 (emphasis added). Similarly, the court has observed that the prospect of an "unjustified patent term extension" has "limited force" in triggering "many double patenting rejections today, in no small part because of the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing." *In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009).

As a leading professor of patent law observes, "the advent of a twenty-year term based on application priority date means that the justification for a double patenting rejection is largely becoming * * * moot." D. Crouch, *Ending the Doctrine of Non-Statutory*

Double Patenting (March 1, 2010).[3] Accordingly, there is nothing pressing about addressing this area of law—which is largely disappearing.

2. Even today, before the doctrine sunsets, double patenting questions seldom arise.[4] The particular issue here is even rarer, having arisen, to our knowledge, at most four times in the last decade—in *Geneva*, *Pfizer*, a prior case involving petitioner, and here. This, too, is independently sufficient to warrant denying certiorari. E. Gressman, *et al.*, SUPREME COURT PRACTICE, § 6.31(b), at 479 (9th ed. 2007) ("how often the issue recurs" informs "importance").

Moreover, the particular issue here is highly unusual if not unique, and would limit the significance of any decision on the merits. On the very same day that it applied for what became the '826 patent, petitioner consciously chose to submit a continuation-in-part application for the not-yet-issued '614 patent—disclosing the same anticancer utility that it separately sought to patent in what became the '826 patent. Making matters more unusual, petitioner chose not to disclose the conclusions of intervening studies to the effect that gemcitabine "proved to be very toxic during *in vivo* tests and thus *not suitable for development as an antiviral agent*" (C.A. App. A314-A318, A315)—even though the initial application was premised solely on antiviral utility. Petitioner and its amici cite no other cases involving this anomalous

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[3] See http://www.patentlyo.com/patent/2010/03/ending-the-doctrine-of-non-statutory-double-patenting.html.

[4] A Westlaw search for the term "double patenting" in the CTAF database for the period 1982 to the present yields 141 cases, of which roughly 110 actually address the substance of a double patenting issue.

fact pattern. But a ruling from this Court would have little real-world impact, as it would apply only in the rare situation where a patentee files a continuation-in-part application that discloses a new utility for a chemical compound and seeks a second patent based on the very same utility.

In sum, even if the issue were otherwise of broad significance, and even if Lilly had preserved the new-found statutory questions on which it seeks review, those questions would not raise issues "beyond the academic or the episodic." *Rice* v. *Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955).

B. Patentees can easily avoid the risk of double patenting by use of proper practices at the prosecution stage.

The question presented is also unlikely to recur because it can easily be addressed by patentees at the prosecution stage. As noted above (at 10-11), when petitioner submitted its continuation-in-part application in December 1984, it had various options that would have entirely avoided the double patenting result it now decries as unfair.

First, petitioner could have filed a terminal disclaimer—*i.e.*, a written statement that petitioner disclaimed the period of the later '826 patent that would extend beyond the expiration of the earlier '614 patent. In fact, the Manual of Patent Examining Procedure suggests a disclaimer in these circumstances: "The use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expirations of patents whereby the inventions covered become freely available to the

public." M.P.E.P. § 804.02 (8th ed., Rev. 7 (July 2008)) (citing cases). Thus, a terminal disclaimer would have addressed petitioner's alleged "early disclosure" concern, and future patentees can take this approach with minimal effort.

Second, petitioner could have declined to add the anticancer disclosure to the December 1984 continuation-in-part application and relied solely on the antiviral utility to attempt to support the gemcitabine compound claim.[5] Indeed, petitioner itself has consistently maintained that it was not obligated to include that disclosure in the '614 patent's application.[6] And "there is no specific statutory requirement that compels an applicant to disclose all properties of chemical compounds or compositions in his application." *In re Davies*, 475 F.2d 667, 671 (C.C.P.A. 1971).

Third, rather than file a separate patent application, petitioner could have included the anticancer method *claims* in the very same continuation-in-part application that disclosed the anticancer utility in the *specification*. Petitioner has never explained why it failed to do so. The Examiner may have limited examination of the application to either the antiviral or anticancer claims, but that would have insulated petitioner's subsequently divided patents from double patenting objections. See 35 U.S.C. § 121; *Pfizer*, 518 F.3d at 1358-1362. And courts will not "rescue [a patentee's] voluntarily filed continuation-in-part appli-

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[5] This assumes, of course, that gemcitabine had an antiviral utility—as petitioner has claimed, notwithstanding its own studies' conclusion.

[6] See Br. of Defendant-Appellant Eli Lilly and Co. 12 (No. 2011-1105) (filed Dec. 22, 2009) ("35 U.S.C. § 101 did not require [Lilly] to disclose the anticancer use").

cation" from a double patenting violation where the patentee, during prosecution, could have taken advantage of a statutory safe harbor. *Perricone* v. *Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).[7]

Each of the foregoing routes was lawful, and each would have avoided petitioner's double patenting problem. Certiorari is not warranted to address an unusual issue that most patentees avoid by taking minimal, proper steps at the prosecution stage—steps that future patentees are even more certain to take. GRESSMAN, *supra*, § 6.31(b), at 479 ("the importance of a case depends on how many other persons, apart from the actual litigants, will be affected").

C. This Court's denial of a prior certiorari petition filed by Lilly confirms that certiorari should be denied.

In addition, on the lone occasion of which we are aware that double patenting was raised in a petition for certiorari—in a case involving the very same petitioner, raising a very similar question, in very similar procedural circumstances—the Court denied it. See *Eli Lilly and Co.* v. *Barr Labs., Inc.*, 534 U.S. 1109 (2002). There, as here, the Federal Circuit invalidated a Lilly patent on "obviousness-type" double patenting grounds. 251 F.3d 955 (Fed. Cir. 2001). And there, as here, over a dissent by Judge Newman, the Federal Circuit denied en banc review. Lilly sought certiorari, asking this Court to decide whether the Federal Circuit erred in invalidating Lilly's patent for

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[7] For this reason, the argument of amicus WLF (Br. 16-18) that the Federal Circuit's decision contradicts rules of the Patent and Trademark Office lacks merit.

double patenting. See Petition for Certiorari i (No. 01-660) (filed Oct. 16, 2001). Despite the support of some of the same amici, Lilly's petition was denied.

Lilly has not explained why this Court, having rejected Lilly's own similar petition in the recent past, should grant review here—let alone where the issues are even less likely to recur and there are vehicle issues. For example, petitioner has not shown that the specific question here arises with frequency (for patentees other than Lilly), or that other developments make review more urgent today. Indeed, as we have shown, the opposite is true: statutory changes have made double patenting even less pressing, and Lilly's particular double patenting problem is easily avoided by taking minimal steps during patent prosecution.

As "this Court does not sit * * * for the benefit of the particular litigants" (*Rice*, 349 U.S. at 74), the fact that the issue may be of particular importance to petitioner does not make it of particular importance "to the public." *Layne & Bowler Corp.* v. *W. Well Works*, 261 U.S. 387, 393 (1923). Petitioner and its amici make sweeping assertions about the importance of double patenting law to encouraging innovation. But none of them substantiates those claims by pointing to recent cases in the lower courts involving similar legal issues or fact patterns, and none of them acknowledges that recent congressional action renders the problem of double patenting largely obsolete. Certiorari should therefore be denied.

III. Equitable Factors, Including Petitioner's Effort To Obtain A Second Monopoly Without Disclosing Information That Undermined Its Earlier Patent, Further Counsel Against Review Of The Decision Below.

In addition to the fact that petitioner seeks error correction on a question of diminishing significance in a case where statutory issues are waived, equitable factors further counsel against review.

Specifically, when petitioner submitted its continuation-in-part application in late 1984, it knew full well that its original patent application had not demonstrated any utility for gemcitabine—which was one of thousands of compounds in a genus mentioned in the original specification. Petitioner also knew full well that, since the original application, it had determined that "[gemcitabine] proved to be very toxic during *in vivo* tests and thus *not suitable for development as an antiviral agent.*" C.A. App. A314-A318, at A315 (emphasis added).

When submitting its continuation-in-part application, however, petitioner said nothing about its recent conclusion that gemcitabine was not a "suitable * * * antiviral agent." *Ibid.* Rather, petitioner said it was disclosing the anticancer data only because, "[a]t the time," "the best mode of using the claimed compounds was as cancer agents."[8] C.A. App. A273. In fact, an-

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[8] Petitioner's assertion is dubious. Even in 1984, the law was clear that "as long as the original application at the time of filing discloses the best mode known at the time of filing, subsequent applications, including continuations in part," do not need to update the "best mode" disclosure. *Johns-Manville Corp.* v. *Guardian Indus. Corp.*, 586 F. Supp. 1034, 1065 (E.D. Mich. 1983); see also *Sylgab*

ticancer treatment was the *only* viable utility for gemcitabine.

Remarkably, petitioner invokes the policy of "public disclosure" and portrays the decision below as "penaliz[ing]" its decision to disclose gemcitabine's anticancer utility in its continuation-in-part application. Pet. 33. Yet for petitioner to refrain from informing the PTO of its own studies' conclusion that gemcitabine was "not suitable for development as an antiviral agent" was anything but candid. As those studies confirmed, disclosure of gemcitabine's anticancer use was critical to a showing of utility—and thus to petitioner's ability to obtain the '614 patent covering gemcitabine, which had not yet issued.

Petitioner is thus attempting to have it both ways—to obtain both the benefit of an earlier patent for an antiviral utility that gemcitabine never had, and the benefit of a later patent for an anticancer utility that gemcitabine had, but was disclosed in the earlier patent and potentially critical to its patentability. If, contrary to fact, petitioner had been entitled to a patent for gemcitabine's antiviral utility, then it was under no obligation to submit a second and newly discovered utility in its continuation-in-part application. And if gemcitabine had no antiviral utility—as petitioner's studies showed—then petitioner's decision to submit the anticancer utility to the PTO was essential to the first patent's validity.

Steel & Wire Corp. v. *Imoco Gateway Corp.*, 357 F. Supp. 657, 658-659 (N.D. Ill. 1973). Petitioner's own case calls this conclusion "widely accepted." *Transco Prods. Inc.* v. *Performance Contracting, Inc.*, 38 F.3d 551, 559 n.9 (Fed. Cir. 1994).

It follows that any result other than that reached by both courts below would be highly inequitable—and would encourage drug manufacturers to withhold vital information from the PTO. Petitioner's conduct renders this case a particularly poor vehicle to resolve the question presented, even if it were otherwise important enough to warrant certiorari (which it is not). As explained below, moreover, petitioner's conduct is exactly what double patenting doctrine was designed to prevent.

IV. The Federal Circuit Correctly Decided The Double Patenting Issue.

Although the foregoing points fully warrant denying certiorari, the petition also fails on the merits. Petitioner's position not only is foreclosed by governing precedent and the patent statute, but also would require unsupportable speculation concerning the basis for the PTO's decisions in this area—and therefore would be unworkable in practice. Certiorari should be denied for these reasons as well.

A. The decision below is compelled by double patenting precedent.

Contrary to petitioner's assertion, the decision below did not "create[] a new, bright-line rule." Pet. i. Rather, the court applied a settled rule in a straightforward way, following *Geneva* and *Pfizer*—rulings that petitioner does not challenge. Indeed, petitioner does not rely on a double patenting case involving a chemical compound that even allegedly conflicts with the unanimous decision below. There is no basis for reversal.

The principle that, for chemical compound claims, double patenting analysis requires consideration of the earlier patent's disclosure has been accepted law

for years. Established in *Geneva* (unanimously) and confirmed in *Pfizer* (unanimously), that principle has never been seriously challenged—and petitioner does not challenge it here, arguing instead that the court below "misapplied" it. But an examination of *Geneva* and *Pfizer* confirms that both cases are on point, and command the result reached below.

In *Geneva*, as here, the earlier patent claimed a chemical compound and disclosed in the specification that it was effective in inhibiting ß-lactamase enzymes. The later patent claimed a method of using the compound to inhibit ß-lactamase. In its double patenting analysis, the Federal Circuit concluded that ascertaining the scope of the earlier compound claim required examining the patent's specification, including the disclosed utility. Based on that disclosure of utility, that later method claim was not "patentably distinct" from the claim to the compound. That is, the method was invalid for double patenting because it "claim[ed] nothing more than [the earlier patent's] disclosed utility as a method of using the * * * compound." 349 F.3d at 1384-1386.

Similarly, in *Pfizer*, the earlier patent claimed compounds and disclosed in its specification their usefulness in treating inflammation and inflammation-associated disorders. The later patent claimed a method of using the compounds for treating inflammation, inflammation-associated disorders, and specific inflammation-associated disorders such as arthritis, pain, and fever. 518 F.3d at 1363 & n.9; Pet. 9a. In evaluating the double patenting question, the Federal Circuit first rejected the contention that it should not consider the earlier patent's specification, then concluded that the later method claims were not "patentably distinct" from the earlier compound

claims. The method claims were therefore invalid for double patenting, because they "merely claim[ed] a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent." 518 F.3d at 1363 & n.8.

The court below closely followed these cases, stating that "[its] prior obviousness-type double patenting decisions in *Geneva* and *Pfizer*, which addressed factual situations closely resembling that presently before the court, control this case." Pet. 7a. As in those cases, the facts here involve (1) an earlier patent claiming a compound and disclosing its utility in the specification, and (2) a later patent claiming that utility as a method of using the compound. There was no "new" rule, just an application of an old one—one that petitioner does not challenge.

Having chosen not to challenge the *Geneva-Pfizer* rule, petitioner is left to assert that the court below misapplied it. *E.g.*, Pet. 24-25, 27. In so arguing, petitioner and its amici mischaracterize the decision as holding that disclosure of a new and nonobvious invention in the specification of a prior patent necessarily results in double patenting. Pet. 24-25.

In fact, the court's decision was much narrower:

> [T]he holding of *Geneva* and *Pfizer*, that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use," extends to any and all such uses disclosed in the specification of the earlier patent.

Pet. 12a. Properly understood, therefore, this decision does not conflict with law or precedent.

B. The decision below is consistent with this Court's precedent and the Patent Act.

Not only is the ruling below a straightforward application of Federal Circuit double patenting precedent involving chemical compositions, it is likewise consistent with this Court's precedent, federal patent law, and public policy.

1. The decision below does not conflict with this Court's precedent.

Petitioner relies heavily on its assertion that the ruling below conflicts with *Miller* v. *Eagle Manufacturing Co.*, 151 U.S. 186 (1894). But *Miller* did not involve "obviousness-type" double patenting at all; it involved same-invention double patenting, which petitioner acknowledges is "clearly not applicable" here. Br. of Defendant-Appellant Eli Lilly and Co. 16, 17 (Fed. Cir. No. 2010-1105) (filed Dec. 22, 2009). That doctrine is based on 35 U.S.C. § 101, which states in the singular that an inventor "may obtain '*a* patent'" for his invention. *Geneva*, 349 F.3d at 1377 (emphasis added).

The inquiry in same-invention double patenting is whether identical subject matter has been claimed twice. *E.g.*, *In re Vogel*, 442 F.3d 438, 441 (C.C.P.A. 1970). In *Miller*, for example, the inventor obtained two patents on a spring device used in a plow apparatus, but "[t]he spring device * * * [was] the same in both patents." 151 U.S. at 196. This Court therefore invalidated the second patent over the inventor's arguments that the patents were directed to different uses. *Ibid.* Because *Miller* did not address obviousness-type double patenting, the language there that petitioner invokes is dictum.

Insofar as *Miller* is relevant, however, it supports the decision below. As petitioner notes, *Miller* permits separately patenting an "improvement of an existing invention." Pet. 19. Here, because gemcitabine is toxic when used to combat viruses, its only use is to combat cancer. Yet petitioner told the PTO that gemcitabine could combat viruses *and* cancer—obtaining two patents: the '614 patent (claiming antiviral utility and specifying anticancer utility) and the '826 patent (claiming anticancer utility). Thus, the '826 patent is not an improvement on the '614 patent; it is effectively a second patent on the same invention—gemcitabine used to fight cancer. In substance, this is no different than *Miller*.

Moreover, contrary to petitioner's intimation (Pet. 19-20), *Miller* repeatedly relied on the *specification* in construing the relevant patents. For example, the Court emphasized that "the specification in each [patent] is substantially the same"; it rested its analysis on "[t]he invention covered by the first patent, as stated in the specification"; and it explained that "[i]t clearly appears from a comparison of the two patents, and their respective specifications and drawings, that the first function or object of the patent of 1879 * * * is identical with the sole object or function covered by the patent of 1881." 151 U.S. at 196, 200, 199; accord *id.* at 202 ("both specifications clearly indicate that the spring device acts with increasing force"); *ibid.* (citing "[t]he specification, forming a part of this patent"); *id.* at 190, 192, 193-197, 201.

Finally, as *Geneva* notes, the specification is a logical place to disclose a chemical compound's utility. Unlike the patents for the plow apparatus—pictures of which appear in the U.S. Reports (*id.* at 192)—gemcitabine's chemical composition claims do not

self-evidently reveal its use. When it comes to chemical compound patents, it only makes sense to determine utility by looking to the specification. Thus, *Miller* and *Geneva* are fully consistent.

2. The decision below does not conflict with the patent statute.

Petitioner also says that the ruling below conflicts with 35 U.S.C. §§ 103 and 120. As noted, those statutory issues were not raised below and are therefore waived. But in any event, both assertions lack merit.

With respect to § 103 (the obviousness statute), petitioner argues that double patenting exists only to "fill a void" where the earlier patent is unavailable as prior art for a § 103 analysis. Pet. 31. Thus, the argument goes, double patenting rules must be suspended whenever one patent is prior art to the other under § 103. This argument fails for three reasons.

First, there is no support for it.[9] On the contrary, it has been specifically recognized that double patenting may exist even though one patent "seemingly enjoys the status of statutory prior art" to the other. *In re Borg*, 392 F.2d 642, 643 (C.C.P.A. 1968).

Second, Lilly is simply wrong that double patenting exists only to "fill a void" where § 103 is inapplicable. Double patenting doctrine exists to prevent a "timewise extension of the right to exclude granted by

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[9] *In re Land*, 368 F.2d 866, 884 (C.C.P.A. 1966), held only that double patenting analysis was "unnecessary" when a § 103 analysis could be applied. The same is true of *In re Ornitz*, 376 F.2d 330, 334 (C.C.P.A. 1967). The language petitioner relies on (at 31 n.11) is dictum and does not suggest, much less hold, that double patenting analysis is erroneous when § 103 applies.

a patent no matter how the extension is brought about." *Van Ornum*, 686 F.2d at 943-944. The doctrine applies when a "new or later patent * * * would operate to extend or prolong the monopoly beyond the period allowed by law." *Miller*, 151 U.S. at 198. Regardless of whether one patent is prior art to the other, the doctrine reflects the longstanding conclusion that a single applicant may not use its control over prosecution of claims to extend a patent's term. *Ibid.*; *Van Ornum*, 686 F.2d at 943-944.

Third, double patenting doctrine and § 103 address distinct issues. The patent statute provides "grounds of rejection which are distinct and separate from 'double patenting,' requiring different inquiries and representing mutually exclusive grounds for rejecting claims." *In re Bowers*, 359 F.2d 886, 889 (C.C.P.A. 1966). Sections 102 and 103 determine whether the applicant is entitled to a patent over the prior art. The double patenting doctrine determines whether the applicant is improperly extending its patent term. Given their "distinct and separate" purposes, petitioner's effort to jumble together section 102/103 analysis with double patenting analysis is illogical. *E.g.*, *Takeda Pharm. Co. Ltd.* v. *Doll*, 561 F.3d 1372, 1376-1377 (Fed. Cir. 2009) (rejecting argument that double patenting should be judged as of the "date of invention" because of §§ 102 and 103).

Petitioner's suggestion that the ruling below conflicts with § 120—which governs the circumstances in which a patent application will be afforded the filing date of an earlier, related application—is also without merit. Filing and priority dates do not factor into the double patenting analysis—and never have—because that analysis turns on patent issue dates. This Court has recognized this basic principle for 150 years:

> [W]here two patents, showing the same invention or device, were issued to the same party, the later one [is] void, although the application for it was first filed; * * * it is the *issue date, not the filing date*, which determines priority to patents to the same inventor on the same machine.

Miller, 151 U.S. at 197 (citing *Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315 (1865) (emphasis added)). Here, the Federal Circuit correctly examined the '614 patent's entire specification, not just a portion thereof based on effective filing dates, because all double patenting violations "rest on the fact that a patent has been *issued* and later issuance of a second patent would continue protection." Pet. 17a (citing *In re Kaplan*, 789 F.2d 1574, 1579-1580 (Fed. Cir. 1986)). As the court below recognized, "there is no support for Lilly's argument." *Ibid.*

3. The decision below does not conflict with, and in fact advances, the policies of the patent law.

Nor does the ruling below conflict with public policy. Rather, the decision is fully consistent with the basic premise that the same invention (or an obvious variation thereof) cannot be patented twice, and the premise that the monopoly conferred upon the inventor is restricted to a fixed term. 35 U.S.C. §§ 101, 154(a)(2); *Geneva*, 349 F.3d at 1377 (citing 35 U.S.C. § 101); see also *Perricone* v. *Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). These rules are meant to benefit the public, not inventors or litigants, and fairness dictates enforcing the patent laws, not creating special rules to address petitioner's assertions of unfairness.

Petitioner says it is being unfairly penalized for "early disclosure." Pet. 34. But there was no "early" disclosure. Petitioner filed the application containing its anticancer method claims on the same day as the continuation-in-part application containing the anticancer disclosure. The decision below is simply the product of petitioner's deliberate prosecution choices. As shown in Part II.B, *supra*, petitioner easily could have avoided a double patenting violation. There is no need to create special rules to address petitioner's unique predicament.

The unfairness here would be to respondent and the public—not petitioner—if the Court were to overturn the finding of invalidity despite an obvious violation of the double patenting doctrine. Fairness does not support allowing petitioner to maintain an improper extension of its patent monopoly, thus preventing competitors from marketing generic drugs and depriving the public of a low-cost alternative to an important cancer medication. The mistake—if a mistake it was—was of petitioner's own making, and it is not this Court's job to correct it.

C. Lilly's implicit approach to double patenting is both new and unworkable.

Notably, petitioner does not offer an alternate rule for double patenting in pharmaceutical cases. But the approach that follows from petitioner's arguments would require courts to determine the dates of invention and carve up specifications based on priority. As we have shown, that approach would be contrary to precedent. See *Miller*, 151 U.S. at 197. Of equal importance, however, it would be entirely unworkable.

Specifically, courts would be mired in determinations about which utility was "first" in time or "essen-

tial" to patentability, and would be forced to consider extrinsic (and often non-public) information, which is inappropriate in a double patenting analysis—and is something courts are ill-equipped to do. Indeed, as the court below noted, petitioner admitted these workability problems at oral argument:

> Where an earlier patent specification describes multiple uses for a compound, a court would be unable to identify the one use that was "essential" or "necessary" to patentability. Indeed, Lilly's counsel repeatedly conceded at oral argument that "many times [a court] may not able to tell" which use was essential to patentability, as would be required under Lilly's test. Additionally, the characterization of the single essential utility might be arbitrary in application. For example, a broadly defined "single" utility might in actuality encompass multiple utilities, leading to significant problems in applying Lilly's proposed standard.

Pet. 12-13a (citations omitted). That the approach urged as an alternative to the analysis below would be arbitrary and unworkable—injecting uncertainty into the patent system—provides yet another reason to deny certiorari.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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